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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,525	11/29/2001	Erlinda M. Gordon	EPE1110-1	6086

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FISH & RICHARDSON, PC  
12390 EL CAMINO REAL  
SAN DIEGO, CA 92130-2081

EXAMINER

SHUKLA, RAM R

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

**Office Action Summary**

Application No.

09/997,525

Applicant(s)

GORDON ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 6 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 11-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11-29-01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Applicant's response filed 2-17-04 has been received and entered.
2. Claims 4-5 and 7-8 have been cancelled.
3. Claims 1-3, 6 and 9-22 are pending.
4. Claims 6 and 11-22 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.
5. This application contains claims 11-22 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
6. Claims 1-3 and 9-10 are under consideration.

***Claim Rejections - 35 USC § 112***

7. In view of applicants' arguments and amendments to claims, the enablement rejection of claims 9 and 10 has been withdrawn.

***Claim Rejections - 35 USC § 102***

The 102 rejection of claims 1-3 and 9-10 as being anticipated by Hall et al (WO 98/44938, 15 October 1998) is withdrawn in view of applicants' arguments and amendments to the claims.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al<sup>1</sup> (WO 98/44938, 10-15-1998) or Hall et al<sup>2</sup> (Human Gene Therapy 11:983-993, 2000) or Liu et al (Journal of Virology 74:5320-5328, 2000) or Gordon et al (Cancer Research 60:3343-3347, 2000) in view of Kurane et al (Annals of Surgery 4:579-585, 1997) and Borrello et al (Human Gene Therapy 10:1983-1991, 1999) for reasons of record set forth in the previous office action of 8-21-03.

***Response to Arguments***

Applicant's arguments filed 2-17-04 have been fully considered but they are not persuasive. Since the enablement rejection and the 102 rejections have been withdrawn, applicants' arguments regarding these issues are moot and therefore have not been discussed.

Applicant's arguments filed 2-17-04 have been fully considered but they are not persuasive. Applicants agree that the cited Hall art is not enabling. However these arguments are not persuasive because the Hall teaches a retroviral article which is injected in tail vein, similar to the method used in the instant application and the transgene present in the vector is expressed in the tumor. It is noted the Hall art uses same tumor model. Therefore, the therapeutic protein encoded by the transgene comprised in the retroviral vector will reach the tumor and produce its inherent effect and the art of Hall is enabling. As for the issue of teaching of a retroviral vector comprising the claimed parts, the art teaches the claimed retroviral

vector (see the description of Hall on pages 7, 15, 20-22 and also the rejection in the previous office action). Applicants have not provided any evidence of substance as to how and why the same method as used by the cited Hall document and the instant application will have two different results.

Therefore, at the time of the invention, an artisan of skill would have been able to modify the vector(s) of Hall et al, Liu et al or Gordon et al by cloning the GM-CSF encoding sequences taught by Borrello et al with a reasonable expectation of success and use the resultant vector for delivering GM-CSF to a tumor in an animal. An artisan would have been motivated to make such a vector because Borrello et al and Khurane et al teach that GM-CSF elicits antitumor effects and because the retroviral vectors of Hall et al, Liu et al and Gordon et al were designed for targeted delivery of therapeutic genes to tumors.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a

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general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (571) 272-0548.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632

A handwritten signature in black ink, appearing to read 'R. Shukla', with a horizontal line extending from the end of the signature.

**RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER**